

REMARKS

Reconsideration is requested.

The specification has been amended to include sequence identifiers to obviate the objection to the specification noted on page 2 of the Office Action dated June 30, 2004. Withdrawal of the objection to the specification is requested.

The pending claims read on the elected subject matter.

Claims 1-15, 18, 19 and 30 have been canceled, without prejudice. Claims 16, 17, 20-29 and 31-39 are pending.

Claims 16 and 17 have been amended to be consistent with, for example, claim 29 and indicate that the vaccine is aimed at preventing evolution of chronic HCV infection. Claims 16 and 17 have been further amended to provide a description of single or specific as described, for example, in the paragraph spanning pages 9-10 of the originally-filed application, and ¶[0057] of the U.S. Patent Application Publication No. 20030147918. No new matter has been added.

To the extent not obviated by the above amendments, the Section 112, second paragraph, rejection of claims 15-39, is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following comments.

The first paragraph of the rejection, spanning pages 2-3 of the Office Action dated June 30, 2004, appears to be a rejection based on an allegation that the Examiner is unable to determine the difference between claims 16 and 18, and claims 17 and 19. Claims 18 and 19 have been canceled, without prejudice, to advance prosecution. The Examiner is requested to advise the undersigned and provide further

clarification in the event the basis of the Examiner's rejection in this passage has not been understood.

As noted above, claims 16 and 17 have been amended to include the further indication from, for example, pages 9-10 of the specification as to the single or specific recitation. The claims are believed to be definite in also indicating that this description also includes the recited parts thereof.

The amendments to claims 16 and 17 further describe the prophylaxis as including prevention of chronic HCV infection, as expressed, for example, in claim 29. The amendments are believed to clarify the Examiner's concerns in first paragraph on page 4 of the Office Action dated June 30, 2004.

The applicants respectfully request the Examiner's consideration of, for example, page 63 (Table 1, plasmids pvHCV-13A, pvHCV-12A, pvHCV-11A, pvHCV-17A, pvHCV-62A, pvHCV-63A, which all contain a HCV-fragment encoding an E1s protein), and page 79, line 10 (Example 15 "The HCV E1s protein (amino acids 192-326) was expressed ..."), which describe and/or provide examples of "E1s" in a manner known in the art.

Withdrawal of the Section 112, second paragraph, rejection is requested.

The Section 112, first paragraph "enablement", rejection of claims 15-39 rejection is traversed. Reconsideration and withdrawal of the rejection are requested as, at a minimum, the Examiner has admitted that one of ordinary skill in the art could have allegedly made and used the invention of at least claims 15-26, 30 and 38-39. See, Section 102 rejections of claims 15-26, 30 and 38-39, as allegedly being anticipated by Houghton (Prospects for Prophylactic and Therapeutic Hepatitis C Vaccines, Princess

Takamatsu Symp. 25:237-243, 1995) and/or Liang (WO 98/21338). Claims 15, 18, 19 and 30 have been canceled, without prejudice. The Section 112, first paragraph "enablement", rejection of at least claims 16-17, 20-26 and 38-39 should be withdrawn as being inconsistent with the Examiner's admission in the Section 102 rejections.

As for the Examiner's specific comments, the applicants note that claim 15 has been canceled above, without prejudice.

The Examiner's assertion that "the specification does not teach any composition that has been shown to prevent disease" on page 4 of the Office Action dated June 30, 2004, is contrary to the Examiner's admission on pages 4-5 of the Office Action that "The specification does provide a working example (Ex. 15) of a useful immunogenic composition which is able to prevent chronic infection of an animal after immunization." The Examiner has not provided any scientific or technical reason why one of ordinary skill in the art would not be able to use the guidance of the present specification, including the demonstrated "useful" working example, to make and use the presently claimed invention. The applicants respectfully submit that the level of ordinary skill in this art has become quite advanced.

The Examiner's comments regarding "material used in" Example 15 of the application as allegedly having been improperly incorporated by reference are not understood and clarification is requested. Specifically, Example 15 of the specification refers to U.S. Patent No. 6,150,134, and the use of vvHCV-11A described therein. Even if this were "essential material", the MPEP indicates in § 608.01(p) that incorporation by reference to a U.S. patent is appropriate. A copy of the patent is attached. No affidavit

or declaration relating to incorporation by reference of any "essential material" from this patent is required according to MPEP § 608.01(p).

Example 15 also makes reference to application PCT/EP99/04342 (WO 99/67285), which has issued as U.S. Patent No. 6,635,257. The applicants note the further procedure described in MPEP § 608.01(p)(I.)(A.)(1.) whereby prior to allowance the Examiner shall enter the U.S. Patent No. of the referenced application in the specification of the referencing application. In the event the Examiner believes the subject matter of application PCT/EP99/04342 is "essential material" the Examiner is requested to either enter an amendment to the specification to refer to the issued U.S. Patent (copy attached) or advise the undersigned that such an amendment should be entered.

The other references referred to in Example 15 of the specification are believed to describe techniques recognized by those of ordinary skill in the art. The Examiner is requested however to advise the undersigned of the specific material which the Examiner considers "essential" and the applicants will be in a position to consider whether an amendment and affidavit or declaration, as described in MPEP § 608.01(p), is appropriate.

As for the Examiner's conclusions regarding the level of skill in the art and amount of experimentation which may be required to practice the claimed invention, the applicants note that the cited U.S. Patent No. 6,635,257, provides a method of inducing immunity against HCV in a chronic HCV carrier. See, claim 14 of the issued patent and compositions for the same (claim 15).

The Examiner's comments with regard to claim 20 on page 5 of the Office Action dated June 30, 2004, is addressed above.

Withdrawal of the Section 112, first paragraph "enablement", rejection of claims 15-39 is requested.

The Section 112, first paragraph "written description", rejection of claim 26 is obviated by the above amendment. Withdrawal of the rejection is requested.

The Section 102 rejection of claims 15 and 30 over Houghton et al. is moot in view of the above.

The Section 102 and Section 103 rejections of Claims 15-26 and 38-39 over Liang (WO 98/21338), is traversed. Reconsideration and withdrawal of the rejections are requested in view of the following distinguishing remarks.

Liang et al. (WO 98/21338) disclose viral-like particles formed inside insect cells and purified from these cells. These particles do not only contain E1 but also Core, E2, and p7 as proteins (see, e.g., amended claims 9 and 20, Example 4 and lines 28-30 on page 3) as well as HCV RNA (see, e.g., amended claim 9 and lines 23-25 on page 9) and an insect cell ER-derived membrane (see lines 15-16 on page 5 and lines 26-30 on page 7). Liang et al. do not teach each and every aspect of the presently claimed invention. Liang et al does not anticipate the presently claimed invention. Withdrawal of the Section 102 rejection of claims 15-26 and 38-39 over Liang et al. is requested.

Further Liang et al does not disclose how to obtain single or specific oligomeric HCV E1 protein, nor compositions comprising them. Liang et al. moreover do not provide a working example for a prophylactic vaccine composition comprising these insect-cell derived viral-like particles, which the Examiner has argued is required with

regard to the alleged lack of enablement of the present application. It is also noted that the presence of viral RNA in a vaccine is highly undesirable. For all these reasons it is submitted that Liang et al. do not anticipate nor render the presently claimed invention obvious. Withdrawal of the Section 102 and Section 103 rejection of the noted clamis over Liang et al. is requested.

Withdrawal of the Section 102 and Section 103 rejections of claims "5-39" (presumably the Examiner meant claims "15-39") over Depla (WO 99/67285 or U.S. Patent No. 6,635,257) is requested in view of the Examiner's comments on pages 4-5 of the Office Action where the Examiner alleges that the compositions of the present application would not be expected to be used by one of ordinary skill in the art, even with the benefit of the teaching of the present specification, to make and use the claimed invention. The Examiner states, in contradiction, on pages 7-8 of the Office Action dated June 30, 2004, that Depla's teaching of "the same ingredient" provides one of ordinary skill in the art with each and every aspect of the presently claimed invention, or an obvious variant of the same. Clarification is requested as the applicants are not in a position from the Examiner's remarks in the Office Action dated June 30, 2004, to respond to apparently contradictory positions of the Examiner.

The Examiner's comments on page 8 of the Office Action dated June 30, 2004, with regard to a Rule 132 Declaration are not understood and clarification is requested in the event the Examiner continues to reject the claims over the cited Depla references.

Withdrawal of the Section 102 and Section 103 rejections over the cited Depla references are requested.

The Examiner is requested to hold the actual and provisional obviousness-type double patenting rejections in abeyance until allowable claims are indicated, at which time the applicants will consider the appropriateness of filing a Terminal Disclaimer.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: \_\_\_\_\_

  
B.J. Sadoff  
Reg. No. 36,663

BJS:  
1100 North Glebe Road, 8th Floor  
Arlington, VA 22201-4714  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100